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South Wales
NP10 8QQ

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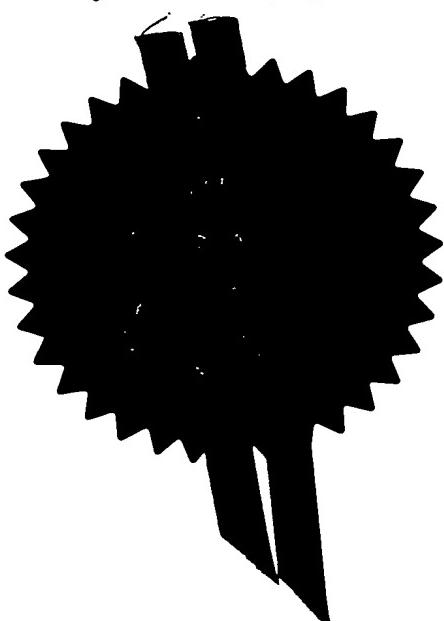
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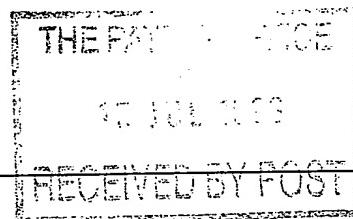
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Request for grant of a patent

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1 Your reference

2 Patent application number

13 JUL 1999

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Full name, address and postcode of the applicant

13 JUL 1999
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Patents ADP number

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4 Title of the invention

INHALER

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6 Priority applications

Country

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8 Statement of Inventorship Needed?		Yes													
9 Number of sheets for any of the following (not counting copies of same document)															
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11 I/We request the grant of a patent on the basis of this application.															
Signature		<u>S.P. Gilholm</u>													
		12 July 1999													
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INHALER

This invention relates to a novel form of inhaler.

- 5 In particular the invention provides a dry powder inhaler which is adapted to be moisture resistant and/or provides improved air flow through the device.

Dry powder inhalers are known, such as CLICKHALER, produced by Innovata Biomed in the UK. Such a device is described in European Patent No 0 539 469.

- 10 Moisture contamination of dry powder inhalers has long been held to be undesirable since the dry powder medicament may become clogged, creating problems in delivering correct dosages of medicament. Furthermore, some medicaments are themselves inherently moisture sensitive. Therefore, there has long been a desire to provide a dry powder inhaler that is resistant to moisture, that is, one that protects a
15 medicament reservoir from moisture contamination either from the environment or from exhalation by a patient using the device.

We have now developed a dry powder inhaler that overcomes or mitigates this problem.

- 20 According to the invention we provide a dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the inhaler is
25 provided with means for preventing moisture from coming into contact with medicament in the reservoir.

- Moisture is prevented from coming into contact with the medicament by a sealing mechanism. In a preferred embodiment, the sealing mechanism of the inhaler will
30 operate by the inhaler being adapted to move from an inoperable position, in which the medicament reservoir is sealed, to an operative position, in which the seal is

reversibly broken so that measurement and/or delivery of a dose of medicament may take place. The sealing mechanism will generally comprise a resilient sealing member positioned at the end of the reservoir adjacent the metering member. Furthermore, the metering member is preferentially biased towards the resilient 5 sealing member to improve the seal provided. Preferably the resilient sealing member is in a fixed position whilst the metering member moves from an inoperable to an operable position and thus from a sealing to a non-sealing position.

The resilient sealing member preferably comprises a cover adapted to fit the base of 10 the medicament reservoir, the sealing member being provided with an aperture to permit transmission of the medicament. The resilient sealing member may comprise any conventionally known material, for example a natural or synthetic rubber, a silicon or a PTFE material, although other similar materials can be contemplated within the scope of this invention

15 In an especially preferred embodiment the metering member is rotatable from an operable to an inoperable position. The metering member comprises one or more, measuring chambers adapted to measure a predetermined dosage of medicament. Thus, in the operable position, the position of measuring chamber of the metering 20 member corresponds with the aperture in the resilient sealing member. In the inoperable position the wall surrounding the metering chamber corresponds with the aperture in the resilient sealing member thus providing a moisture tight seal.

The metering member may be a frusto conical member such as described in 25 European Patent No 0 539 469. Thus, the metering member may comprise a frusto conical member wherein the outer side wall of the cone contain measuring chamber or chambers. Such a side wall can, preferably, include a plurality of spaced-apart measuring chambers.

The use of the frusto-conical shape in the wall of the metering member containing the measuring chambers allows a good seal to be obtained between the metering member and a seat against which the frusto-conical wall mates.

- 5 In a preferred embodiment the frusto conical metering member may itself comprise a combination of a frusto conical dispensing member and a frusto conical moisture resistant sleeve which forms a snug fit over the dispensing member. The moisture resistant sleeve may itself be moveable eg rotatable from a sealing to a non-sealing position as herein before described. Such a moisture resistant sleeve may comprise
10 any conventionally known material but is preferentially a plastics material eg the same material as the metering member.

The dispensing member and the moisture resistant sleeve can, preferentially, be adapted so as to act together as a medicament measuring/dispensing member. The preferred metering member comprises a dispensing member provided with one or more dispensing chambers and a moisture resistant sleeve provided with one or more dosage measuring chambers. Preferably the metering member comprises a plurality of dispensing chambers and a plurality of measuring chambers, it is especially preferred that the metering member comprises an equivalent number of dispensing
20 chambers to measuring chambers.

We have especially found that if the moisture resistant sleeve comprises a frusto hemispherical cone, then an improved seal is achieved between the medicament reservoir and the sealing member. When a hemispherical cone is used, the base of the reservoir may be arcuate so as to form an improved seal with the cone. Thus, it is especially the outer walls of the cone which are hemispherical. The inner walls of the cone are preferably contoured to form a good mate with the frusto conical dispensing member.

30 Thus, in operation, the device may be moved to a first position in which the medicament is transferred to a first measuring chamber in the moisture resistant

sleeve, the device is then moved to a second position in which medicament is transferred from the measuring chamber to a dispensing chamber in the dispensing member and then to a third position where medicament is delivered to the inhalation passage.

5

The dispensing member may be a conventionally known member such as a frusto conical member described herein and in EP 0 539 469. However, we have also found the use of a moisture resistant sleeve permits a dispensing chamber to be provided with an air inlet. Previously, the use of an air inlet was felt to be undesirable since it might effect the accuracy of the measurement of the medicament dose. However, by use of a system wherein the medicament is first transferred to a measuring chamber, the chamber in the dispensing member may be provided with an air inlet without any loss in accuracy of the dosage delivered. Furthermore, improved air flow provides greater likelihood of complete emptying of the dispensing chamber.

10 15

Thus according to an alternative feature of the invention we provide a dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the metering member comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.

20 25

In the preferred embodiment the dispensing member is provided with one or more medicament dispensing chambers, e.g. cups, said chambers being provided with an air passage so as to provide a flow of air through the air passage and the chamber into the inhalation passage upon operation of the device.

30

By the term dry powder we mean a medicament in finely divided form.

The invention will now be described by way of example only and with reference to the accompanying drawings in which:

5 Figure 1 is a perspective view of an inhalation device of the invention;

Figure 2 is a schematic representation of the sealing and measuring mechanism.

Figure 3 is a perspective view of a moisture resistant sleeve comprising a frusto hemispherical cone, and

10 Figure 4 is a cross-sectional view of a moisture resistant sleeve comprising a frusto hemispherical cone.

With reference to Fig 1, a dry powder inhaler (1) comprises a medicament reservoir (2) comprising an essentially conical member; an inhalation passage (3) and a metering member (4). The inhalation passage (3) is connected to the medicament reservoir (2) by a reservoir support (5) and is itself connected to recess (6) which provides a seat for the metering member (4). The metering member (4) is rotatable about an axis (7) from a medicament receiving position, to a medicament delivery position and then to an emptying position to allowing any residual medicament to be 20 emptied into a waste box (8).

The recess (6) is essentially frusto conical in shape to enable it to provide a seal for the metering member (4). The metering member (4) comprises a frusto conical moisture resistant sleeve (9) which forms a snug fit between recess (6) and a dispensing member (10). The dispensing member (10) is also provided with a back plate (11).

25 The moisture resistant sleeve (9) abuts against the resilient seal (9a) to form a moisture resistant seal.

30 The moisture resistant sleeve (9) is also provided with a plurality of measuring chambers which comprise apertures (12) dimensioned to measure a predetermined

amount of medicament and to fit over chambers (13) in the dispensing member (10). In a preferred embodiment, each of the chambers (13) are also provided with an air inlet (14). The medicament reservoir (2) is also provided with a moisture resistant, eg foil, cover (15) at it's end (16) distal from the metering member (4).

5

With reference to Figure 2, in which Figure 2a the metering device is in a closed position,

Figure 2b the metering device is in a measuring position,

Figure 2c the metering device is in a seal transitory position,

10

Figure 2d the metering device is in a medicament transfer position,

Figure 2e the metering device is in a medicament delivery position; and

Figure 2f the metering device is returned to the closed position.

15

In Figure 2a the metering device 4 is in the closed position and the medicament reservoir (2) is isolated and a seal formed between the sealing member (17) and the surface (18) of the moisture resistant sleeve (9). In Figure 2b, the moisture resistant sleeve (9) is rotated in an anti clockwise direction so that the aperture (12) corresponds with the aperture (19) in the sealing member (17). The aperture (19) forms a cup with the surface (20) of the dispensing member (10).

20

In Figure 2c the moisture resistant sleeve (9) is further rotated so that the aperture (19) sits below the sealing member (17). The internal edge (21) of the sealing member (17) scrapes any excess medicament from the aperture (19) to leave a measured dose.

25

In Figure 2d the dispensing member (10) is rotated in an anticlockwise direction so that the dispensing chamber (13) corresponds with the aperture (12) allowing medicament to transfer from the aperture (12) to the dispensing chamber (13).

In Figure 2e both the dispensing member (10) and the moisture resistant sleeve (9) are rotated anticlockwise to expose them and the medicament to the inhalation passage (3). The patient can then inhale the medicament.

- 5 In Figure 2f the inhalation device remains in the closed position ready for use.

With reference to Figures 3 and 4, a moisture resistant sleeve (9) comprises a frusto hemispherical cone (22) wherein the outer surface (23) is arcuate. The inner surface (24) acts as a female member to form a snug fit with the frusto conical dispensing member (10). Downward pressure in the medicament reservoir (2) ensures a constant moisture tight seal between the sealing member (17) and the frusto hemispherical cone (22). Furthermore, referring to Figure 4c, the leading edge (25) of the sealing member (17) is capable of acting as a scraper or a cleaning edge, removing any excess medicament from the measuring chamber upon rotation of the metering member.

A variety of mechanisms may be used for the operation of the inhaler. One preferred mechanism is for movement from the closed to the measuring position to be achieved by removal of a mouth piece which is operably linked to the moisture resistor. Movement from the measuring position to the transitory position would use a mechanism similar to that described in EP 0 539 469, e.g. by depressing the button half way. Movement to the transfer position being achieved by further depressing the button, and then depression completely, moving the metering cone and the moisture resistor to the delivery position.

CLAIMS

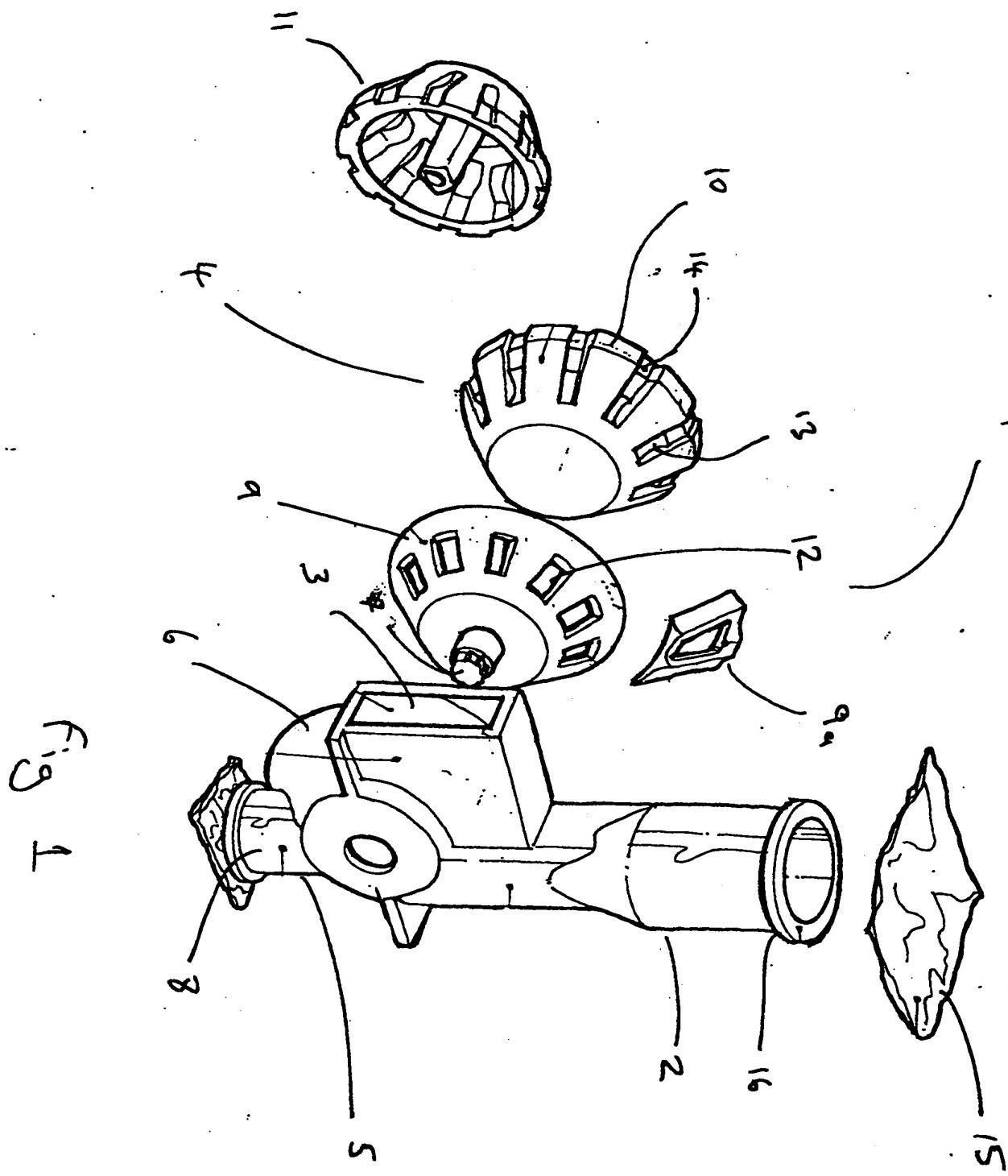
1. A dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the inhaler is provided with means for preventing moisture from coming into contact with medicament in the reservoir.
- 10 2. A dry powder inhaler according to Claim 1 wherein the means for the prevention of moisture comprising a sealing mechanism.
- 15 3. A dry powder inhaler according to Claim 2 wherein the sealing mechanism is adapted to move from an inoperable position in which the medicament reservoir is sealed, to an operable position in which the seal is broken so that measurement and/or delivery of a dose of medicament may take place.
- 20 4. A dry powder inhaler according to Claim 2 wherein the sealing mechanism comprises a resilient sealing member positioned at the end of the medicament reservoir adjacent the metering member.
- 25 5. A dry powder inhaler according to Claim 4 wherein the metering member is biased towards the sealing member.
6. A dry powder inhaler according to Claim 3 wherein the metering member is rotatable from an operable to an inoperable position.
- 30 7. A dry powder inhaler according to Claim 1 wherein the metering member comprises a combination of a dispensing member and a moisture resistant sleeve.

8. A dry powder inhaler according to Claim 7 wherein the moisture resistant sleeve acts as a medicament measuring device.
- 5 9. A dry powder inhaler according to claim 7 wherein the moisture resistant sleeve is a frusto hemispherical cone.
- 10 10. A dry powder inhaler according to Claim 1 wherein the device may be moved to a first position in which the medicament is transferred to a measuring chamber, the device is then moved to a second position in which medicament is transferred to a dispensing chamber and to a third position where medicament is delivered to the inhalation passage.
- 15 11. A dry powder inhaler according to Claim 1 wherein the dispensing chamber is provided with an air passage.
- 20 12. A dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the metering member comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.
- 25 13. A dry powder inhaler according to Claim 12 wherein the second member is provided with one or more medicament receiving cups, said cups being provided with an air passage so as to provide a flow of air through the passage and the cup into the inhalation passage upon operation of the device.
- 30

14. A dry powder inhaler substantially as described with reference to the accompanying drawings.

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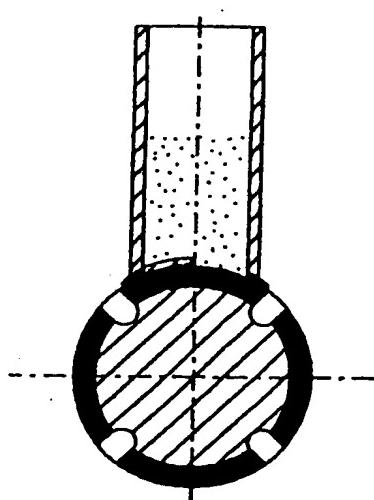
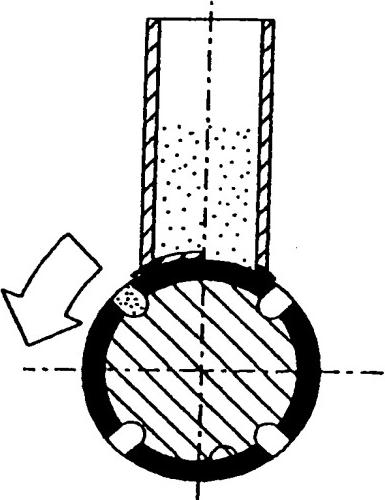
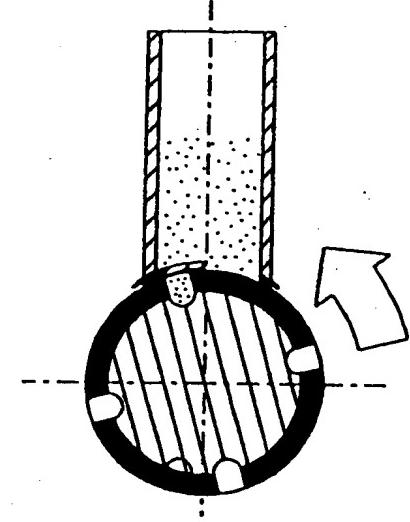
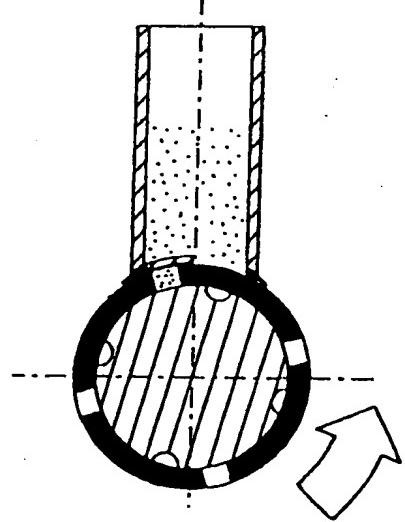
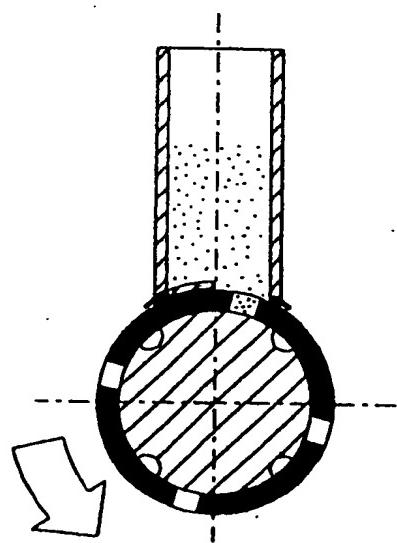
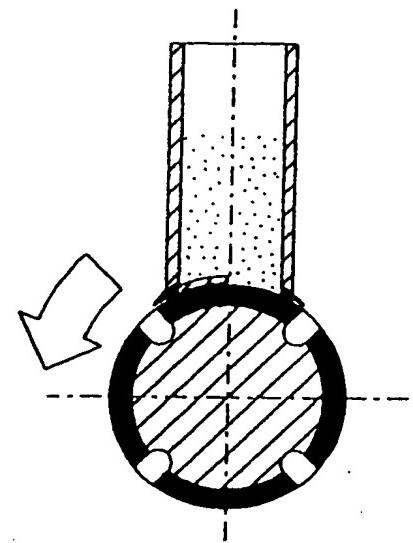


Fig. 2.

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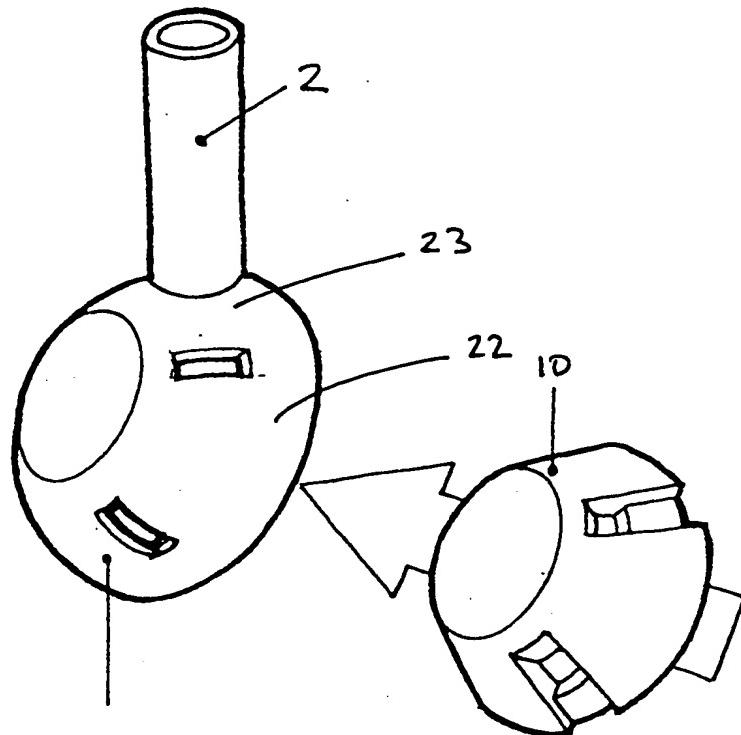
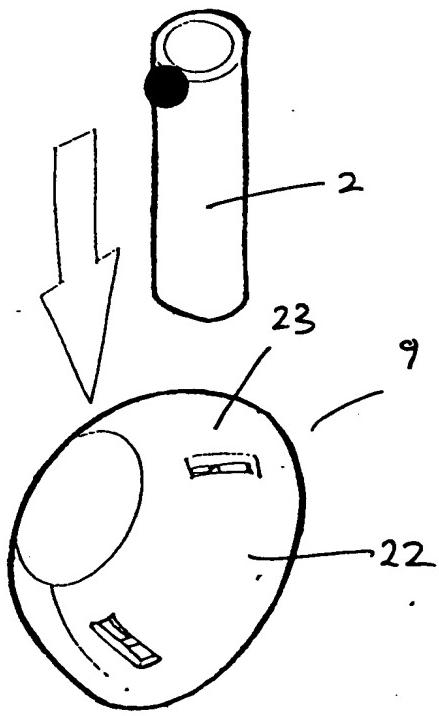


Fig. 3

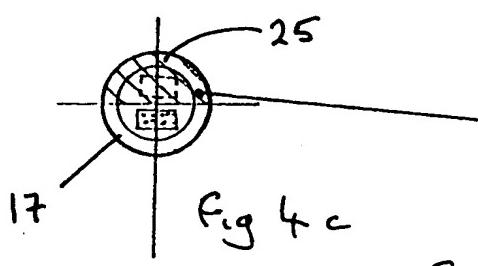


Fig. 4c

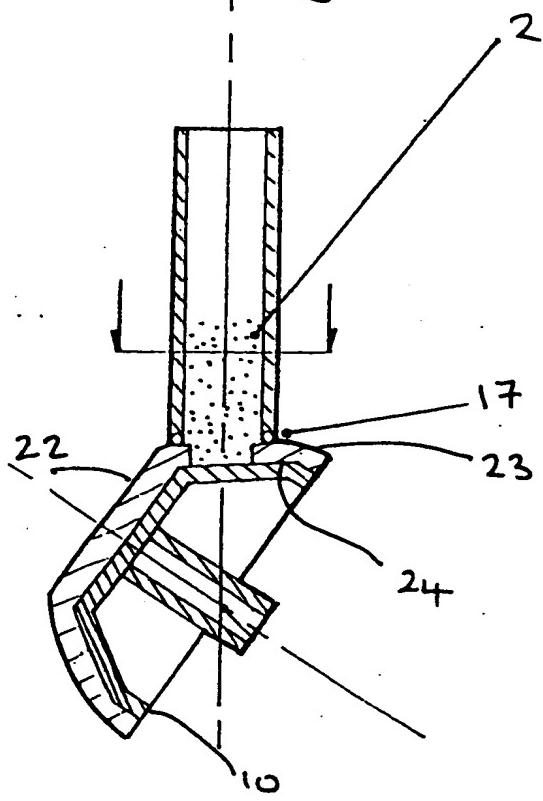


Fig. 4a

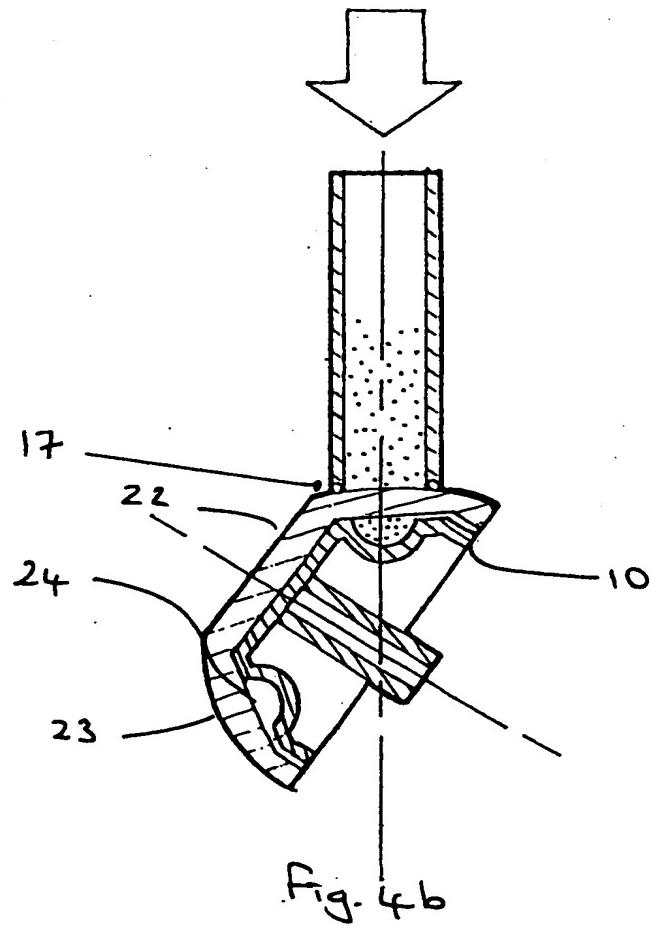
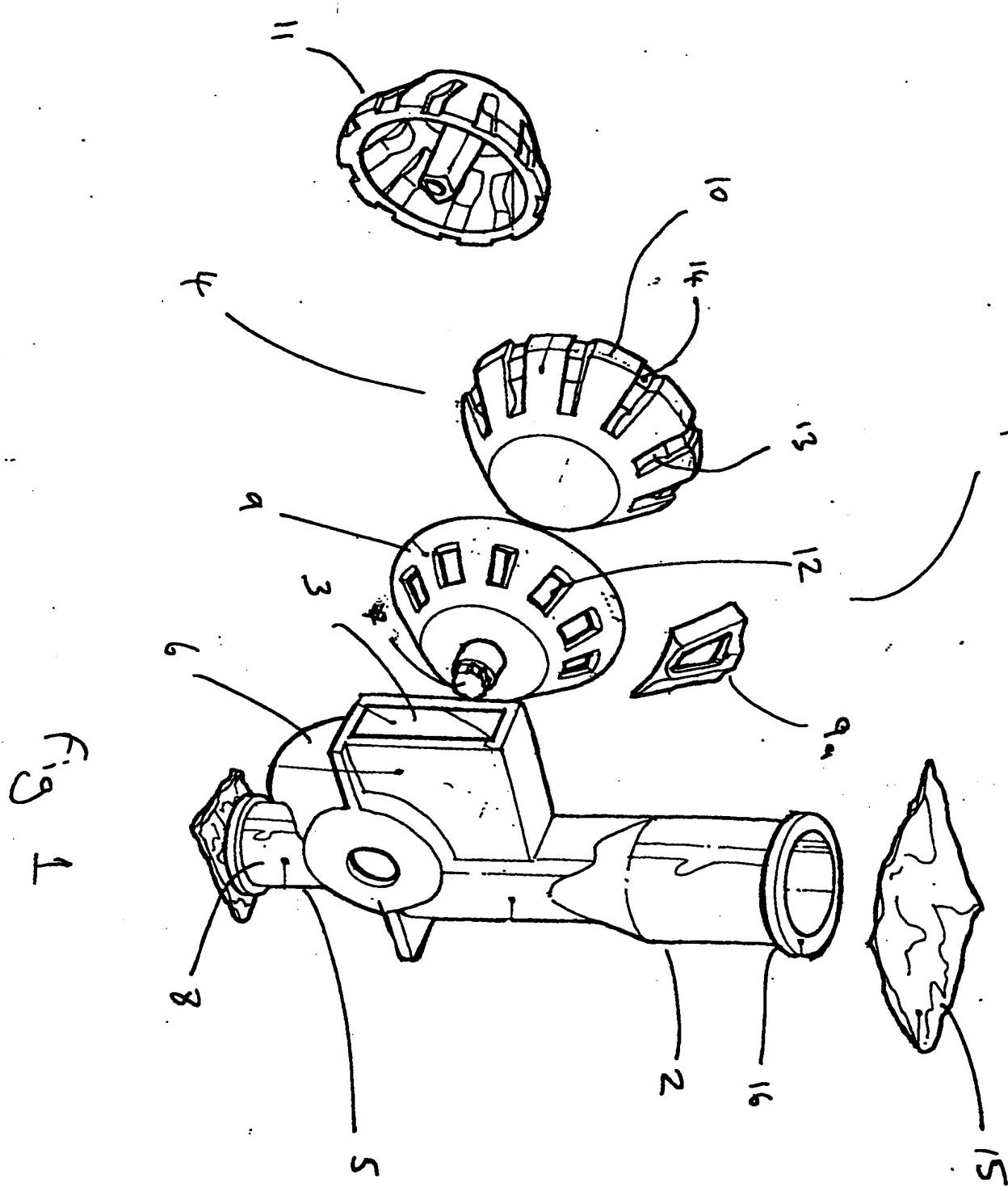


Fig. 4

Fig. 4b

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